

REMARKS/ARGUMENTS

Claims 1-24 are pending, of which claims 16-24 are withdrawn.

Claims 1-8 and 10-15 are rejected as unpatentable over Chieng et al. in view of Vandamme, Liu, and Hirt. Claim 9 is rejected as unpatentable over the above references and further in view of Havermeyer et al. Applicants respectfully traverse the rejections for at least the following reasons.

Claim 1 recites, among others, “polymerizing a bicontinuous microemulsion” to form a porous polymer, wherein a drug is initially dispersed at least in the matrix portion of the polymer and is releasable from the matrix portion into the pores.

The Office action admits that the primary reference, Chieng, does not teach the inclusion of a drug dispersed in at least the polymer matrix and is releasable therefrom. However, the Office action asserts that these features would be obvious over Vandamme. In particular, the Office action asserts that it would be obvious to modify the microemulsion of Chieng by adding an ophthalmic drug to the hydrophobic portion during the polymerization process, in view of Vandamme. The Office action also asserts that it is inherent that a drug in a polymeric matrix will diffuse into the pores and will be released upon contact with a liquid. Applicants respectfully disagree with these assertions.

First, the Office action does not seem to distinguish between “microemulsion” and the “polymer” (polymer matrix) formed from the microemulsion. They are not the same thing. Careful review of Vandamme reveals that it discloses eye drops formed of a microemulsion wherein a drug is dispersed in the oil phase of the microemulsion. According to Vandamme, “The microemulsions are liquid” (p. 16, right col., Sec. 1.3). Vandamme does not disclose or suggest that the oil phase in the eye drops should be solidified by polymerization. In fact, a person skilled in the art would understand that the specific microemulsions disclosed in Vandamme are not polymerizable. Further, according to Vandamme, the main advantage of its microemulsion is “the increase in the solubilization of the drugs” (see p. 22, col. 1, last two lines of Vandamme). A person skilled in the art would understand that polymerizing the oil phase would destroy this advantage. Thus, Vandamme in fact teaches away from polymerizing its

microemulsion because, while the microemulsion is a liquid suitable for use in eye drops, any polymer matrix formed from the oil phase would no longer be in the liquid form and the resulting polymer would not be suitable for use as eye drops. Vandamme also teaches away from delivery of the drug in a solid carrier.

Further, Vandamme does not disclose or suggest that the drug would still be releasable if the oil phase were polymerized. There is no evidence in the cited references to support the assertion in the Office action that a drug dispersed in the oil phase would be inherently releasable after polymerization of the oil phase. As discussed in the applicants' response to the first Office action, a skilled person would believe that it is difficult for the drug to release from a matrix portion formed from a monomer phase. The newly cited references do not provide any contrary information. Even assuming, for the sake of argument, that the oil phase of the microemulsion taught by Vandamme were polymerizable, a person skilled in the art would expect that a drug dispersed in the oil phase of the microemulsion as taught by Vandamme, following polymerization, may be trapped inside, or bonded to, the polymer matrix formed as a result of polymerization. None of the cited references disclose or suggest how such trapping or bonding could be avoided if a drug is dispersed in the microemulsion before polymerization. Thus, the persons skilled in the art would not be motivated to do so.

To summarize, Vandamme teaches that for ocular drug delivery, the drug should be dispersed in a liquid and be contained within nano-sized droplets (see Abstract and the Conclusion section of Vandamme); and does not provide any motivation for dispersing the drug in a polymer matrix, or any solid carrier. It is clear from Chieng that the polymer material formed from its microemulsion after polymerization is a solid (e.g. the captions of Figures 4 and 5 of Chieng each states that the images shown are those of "the polymeric solid formed from microemulsion sample"; also see caption of figure 6). Therefore, Vandamme not only fails to provide any motivation for, but also teaches away from, adding the drug to the monomer phase of the microemulsion of Chieng that is to be polymerized into a solid.

Therefore, it would not have been obvious for the skilled person to modify Chieng in view of Vandamme to arrive at the subject matter claimed in claim 1 of the present application.

The other cited references, either alone or in combination, do not cure the above defects of Chieng and Vandamme.

Accordingly, it is respectfully submitted that claim 1 is patentably distinguishable from the cited references of record for at least the above reasons. Likewise, claims 2 to 15, which depend from claim 1 directly or indirectly, are also patentably distinguishable from the cited references of record for the same reasons and because each such claim includes a further limitation that distinguishes the claimed invention.

Withdrawal of the rejections is thus respectfully requested.

In view of the foregoing, favorable re-consideration of this application is earnestly solicited.

Respectfully submitted,

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